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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/381,598 09/20/1999 MASAHIKO MIHARA 350292000800 4167

25225 7590 05/30/2002

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/30/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/381,598

Applicant(s)

MIHARA, MASAHIKO

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 14-22 and 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14-22 and 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Formal Matters

Claims 14-22, 24-32 are pending and under consideration.

Response to Arguments

Applicant's arguments filed 3/4/2002 have been fully considered but they are not persuasive, for the reasons set forth below.

The rejection of claims 14-22 under 35 USC § 102(b) as being anticipated by Vink et al. has been withdrawn based on Applicant's arguments.

The rejection of claims 14-22 under 35 USC § 112, first paragraph has been withdrawn, based on Applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vink et al. (1990).

Vink et al. teaches the administration of anti-IL-6 receptor antibodies (page 998, second column, third paragraph). It is an inherent property of the anti-IL 6 receptor antibodies to suppress sensitized T cells. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. See also

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Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC
2001)1300-1304 (CAFC 4/20/01)

Applicant argues that the claimed method is directed to a different use than the teaching of Vink et al. However, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. The instant claims are directed to a method of administration of anti-IL-6 receptor antibody to a subject, which is also disclosed in the Vink reference. The Court in Ben Venue Laboratories found that preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims. This is analogous to the instant case where the preamble language of claim 24 is directed to suppressing T cells, but there are no manipulative differences in the method steps between the teaching of Vink et al. and the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-22, 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gijbels et al (1995) in view of Vink et al. (1990).

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Gijbels et al. teaches the administration of antibodies to IL-6 in the EAE model of multiple sclerosis (page 799, Table I). The administration of the mAB to IL-6 significantly reduced the development of EAE, both in actively induced EAE and in the adoptive transfer model of EAE. Gijbels does not disclose administration of anti-bodies to IL-6 receptor. Vink et al. teaches the administration of anti-IL-6 receptor antibodies (page 998, second column, third paragraph) as well as antibodies to IL-6 (page 998, Figure 1). These antibodies both block the action of IL-6 (page 998, column 2, third paragraph). Given the teaching of Gijbels of the beneficial effect of blocking the effect of IL-6 in the EAE model, along with the teaching of Vink that the effect of IL-6 can be neutralized by antibodies to both IL-6 and IL-6 receptor, it would have been obvious to one of skill in the art at the time the invention was made to practice a method of administration of anti-IL-6 receptor antibodies to treat MS. The motivation is provided by Gijbels who concludes that the protective effect of anti-IL-6 in EAE might have therapeutic effect in inflammatory conditions of the CNS, including MS (page 804).

Conclusion

No claim is allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
May 29, 2002



DAVID S. ROME
PRIMARY EXAMINER